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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,546	09/05/2003	Yatindra Joshi	4-31972B	8175

1095 7590 08/14/2006

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,546	JOSHI ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/16/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 24-35, 38 and 39 are rejected under 35 U.S.C. 102(e) as being anticipated by Midha US 2003/0170181 A1.

Midha discloses a method for preventing abuse of methylphenidate by orally administering a pulsatile system comprising methylphenidate (abstract; and paragraphs 0015-0016). Methylphenidate is dispersed in a matrix or coated with a polymeric coating comprising cellulosic polymer, acrylic and methacrylic copolymer, vinyl polymers and copolymer such as polyvinyl pyrrolidone (paragraphs 0070-0072). The system further comprises pH buffering agents, and natural and synthetic gums such as sodium alginate (paragraph 0079). Additional acid for preparing acid addition salts includes sodium hydroxide, calcium hydroxide, and the like (paragraph 0089).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Midha US 2003/0170181 A1.

Midha is relied upon for the reason stated above. Midha does not explicitly teach the amounts of active and polymer in the delivery system. Midha further does not teach the molecular weight of the polymer. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the amounts of ingredients in the dosage form to obtain the claimed invention, because Midha teaches the use of the same ingredients for the same purpose, namely, novel dosage form useful for the treatment of patient with a methylphenidate-responsive condition, and reducing the likelihood for abuse of methylphenidate.

Regarding the molecular weight, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select the claimed molecular weight, because Midha teaches the same polymer in the matrix. Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical

structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Claims 24-39 are rejected under 35 U.S.C. 102(a) as being anticipated by Midha, in view of Mulye US 6,437,000.

Midha is relied upon for the reason stated above. Midha does not explicitly teach the amounts of active and polymer in the delivery system.

Mulye teaches pharmaceutical composition in the form of tablet or capsule comprising more than 5% active agent; about 1% to about 50% matrix polymer (gel forming polymer), *e.g.*, methyl methacrylate polymer, ethyl cellulose, polyvinyl acetate, polyvinyl chloride, or polystyrene; and inorganic salt, *e.g.*, calcium carbonate (columns 3-4). The active agent includes methylphenidate, amphetamine, or epinephrine (column 5, lines 63-67). Thus, it would have been obvious to one of ordinary skill in the art to modify the delivery system of Midha in view of the teaching of Mulye to obtain the claimed invention, because Mulye teaches a dosage form useful to deliver the same active ingredient desired by Midha.

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mehta et al., Bettman et al., Davies, and Steiner are cited as of interest for the teachings of formulations containing methylphenidate.

Correspond nc

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R 6:00 am to 4:30 pm; Thurs. (telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Tran
Primary Examiner
Art Unit 1615